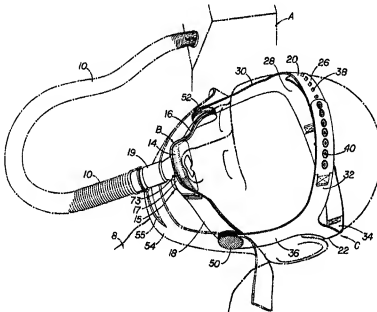




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US98/15588 (22) International Filing Date: 24 July 1998 (24.07.98)	(81) Designated States: AU, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>	(30) Priority Data: 08/899,806 24 July 1997 (24.07.97) US
(71) Applicant: RBSPIRONICS GEORGIA, INC. [US/US]; 1501 Ardmore Boulevard, Pittsburgh, PA 15221 (US).		(72) Inventors: CORREA, Jose, Luis; 1108 12th Street, North Bergen, NJ 07047 (US). FONTAYNE, Diego; 20 East Maple Street, Teaneck, NJ 07666 (US). KIRK, Karl, Dallas, III; 5th floor, 30 Bond Street, New York, NY 10012 (US). COLLINS, James, T., III; Apt. 2E, 449 West 44th Street, New York, NY 10036 (US).
(74) Agent: BOSS, Gerald, R.; Troutman Sanders LLP, Suite 5200, 600 Peachtree Street, Atlanta, GA 30308-2216 (US).		

(54) Title: NASAL MASK AND HEADGEAR



(57) Abstract

A nasal mask assembly (B) having a nares seal (14), a pair of lateral support members (16, 18), an associated headgear assembly (C) where the mask assembly is interconnected to the headgear assembly so as to be adjustable linearly, and angularly with respect to the headgear assembly.

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NASAL MASK AND HEADGEAR

BACKGROUND OF THE INVENTION

This invention relates generally to a nasal mask for providing pressurized gas to a patient and more particularly to a nasal mask which only encloses the nares of a patient which utilizes a pair of lateral support arms which in combination with an associated headgear support the mask.

Masks are used for various reasons. Typically masks are interconnected with a source of breathable fluid to be inhaled by a patient. These masks are used for anesthesia and also for providing positive air pressure to a patient in the treatment of obstructive sleep apnea. In the treatment of obstructive sleep apnea, positive air pressure is provided to a patient while the patient is sleeping.

Accordingly, in the treatment of obstructive sleep apnea, mask comfort is important to ensure that the patient may sleep and also to ensure that the patient complies with the treatment. For the treatment of obstructive sleep apnea, the mask must provide a sufficient seal to enable pressure to be maintained within the airway of the patient. Typical masks are bulbous and enclose a large portion of the nose and engage the face of the patient. These masks tend to produce a claustrophobic effect on the patient. Furthermore, these masks generally irritate the bridge of the nose and parts of the patient's face hindering patient comfort.

Also, generally these masks are secured to a patient's head by straps to ensure that a tight seal is had, thus further presenting pressure onto the patient's nose. Additionally, the positioning and securing of the mask with the straps is cumbersome and time consuming. United States Patent No. 5,517,986 illustrates a headgear assembly for a gas delivery mask utilizing straps.

Some masks have been developed which are not bulbous nor fit on a patient's nose, but consist of a pair of elongated flange members which are inserted directly into the patient's nares. United States Patent No. 5,042,478 discloses such a mask. While this type of mask is suitable for its intended purpose, the presentation of air directly into the patient's nares is awkward and generally uncomfortable to the patient.

Accordingly, it is an object of the present invention to provide a nasal mask which is comfortable to wear by a patient and which is easily secured for providing a seal around the nares of a patient;

Furthermore, it is an object of the present invention to provide a nasal mask which solely encloses the nares of a patient;

Also, it is an object of the present invention to provide a nasal mask and headgear assembly which is easy to position onto a patient and which is adjustable to accommodate the physical characteristics of an individual patient;

Additionally, it is an object of the present invention to provide a nasal mask assembly which matingly adapts to the cheeks of a patient which in combination with a headgear assembly supports the mask.

SUMMARY OF THE INVENTION

A nasal mask assembly for providing gas from a gas source to a patient includes a nare seal having a surface for encircling the nares of a patient. The nare seal defines a gas opening permitting gas from the gas source to enter into the nares of a patient. A nare seal support carries the nare seal.

DESCRIPTION OF THE DRAWING

The construction designed to carry out the invention will hereinafter be described, together with other features thereof.

The invention will be more readily understood from a reading of the following specification and by reference to the accompanying drawings forming a part thereof, wherein an example of the invention is shown and wherein:

Figure 1 is a top perspective view of a patient utilizing a nasal mask assembly and headgear assembly according to the present invention;

Figure 2 is a side perspective view of a patient utilizing the nasal mask assembly and headgear assembly according to the present invention;

Figure 3 is a rear view of the nasal mask assembly and headgear assembly according to the present invention;

Figure 4 is an exploded view of the nasal mask assembly according to the present invention;

Figure 5 is side view illustrating the pre inflation position of the nare seal according to the present invention;

Figure 5A is an operational view illustrating the pre and post inflation positions of the nasal mask with respect to a patient nares;

Figure 6 is a rear perspective view of the nasal mask assembly according to the present invention;

Figure 7 is a view taken along line 7-7 of Figure 6 illustrating the pre and post inflation of the nare seal according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Now reference will be made with respect to the drawings for understanding of the preferred embodiment of the invention.

As shown in Figure 1, a positive pressure device A provides gas under positive pressure to a patient 8 through a conduit 10. Conduit 10 is in fluid communication with nasal mask assembly B which provides the pressurized gas to the nares of the patient. Headgear assembly C maintains the positioning of nasal mask assembly B with the patient's nares. In this manner, the patient's vision is not obstructed.

As shown in Figures 1 and 2, nasal mask assembly B includes flexible nare seal 14 and nare seal support 15. Nare seal 14 seals the nares of the patient when positive pressure is applied to nasal mask assembly B. Nare seal support 15 includes first and second support arms 16 and 18 which extend outwardly from central support 17. First and second support arms 16 and 18 preferably traverse the face of the patient and rest against the cheekbones of the patient. In this manner, the force required to maintain a tight seal between nare seal 14 and the nares of the patient are transferred to a sturdy bone structure. A conduit receptor 19 attaches to conduit 10 for communicating pressurized gas from the conduit into the interior of nare seal 14.

As further shown in Figures 1 and 2, nasal mask assembly B is secured to headgear assembly C. Headgear assembly C includes first headgear member 20 and second headgear member 22 which are interconnected to define a support structure for supporting nasal mask assembly B in fluid communication with the patient's nares. First headgear member 20 and second headgear member 22 are preferably mirror images. First headgear member 20 is generally "Y" shaped having a first forward lateral arm 26 and a first rearward lateral arm 28 disposed rearwardly of forward lateral arm 26. First headgear member 20 also includes first depending arm 30. In the preferred embodiment, first forward lateral arm 26, first rearward lateral arm 28 and first depending arm 30 are of a unitary construction such that first depending arm 30 depends downward from the junction of forward lateral arm 26 with rearward lateral arm 28. Second headgear member 22, being of a mirror image of first headgear member 20, includes second forward lateral arm 32, second rearward lateral arm 34 and second depending arm 36 and is also preferably of unitary construction.

First and second headgear members are designed to matingly attach to one another. In this manner, first and second headgear members are assembled such that first and second forward lateral arms 26 and 32 encircle the forehead of the patient while first and second rearward lateral arms 28 and 34 encircle the sides and back of the patient's head. First and second depending arms 30 and 36 depend downward along the patient's head in front of the patient's ears. Also, when first and second headgear members 20 and 22 are assembled, they define head opening 45 which receives the crown of the patient leaving a predominant portion of the patient's head unencumbered.

In the preferred embodiment, first forward lateral arm 26 includes pegs 38 and second forward lateral arm 32 includes peg receptacles 40. Also, first rearward lateral arm 28 includes peg receptacles 42 and second rearward lateral arm 34 includes pegs 44 enabling first and second headgear members 20 and 22 to be selectively interconnected depending on the head parameters of the patient to provide a secure fit. By providing sufficient interconnecting elements, headgear assembly C may be constructed to fit an adult, child or even an infant. Furthermore, first and second headgear members 20 and 22 are formed from a semi-rigid plastic material providing a semi-rigid support. The semi-rigid support retains its shape when assembled and transfers support forces along the entire periphery of headgear assembly C.

As further shown in Figures 1 and 2, nasal mask assembly B attaches to headgear assembly C via contact connectors 46 and 48. Preferably, contact connectors 46 and 48 include hook and loop fasteners such as Velcro trademark with a respective member being attached to the inside surface of first and second depending arms 30 and 36 and a correspondingly mating member attached to the exterior of support arms 16 and 18. In this manner, support arms 16 and 18 of nasal mask assembly B may be readily attached linearly and at any angle with respect to headgear assembly C for cooperating with the physical characteristics of the patient. Also, since headgear assembly C is semi-rigid and retains its shape, removal of the mask may be achieved by merely releasing either first or second support arm 16 or 18 from its respective mating attachment of the respective first or second depending arm. Strap connectors 50 and 52 attach support strap 54 to headgear assembly C. Support strap 54 includes slit 55 and may be positioned under the chin of the patient or encircling the scalp. Strap connectors 50 and 52 preferably include hook fasteners such as Velcro trademark and matingly engage support strap 54 which is preferably assembled from the fastening component of Velcro trademark.

As shown in Figures 2, 3, 4, 5, 5A, 6 and 7, nare seal 14 is a soft membrane preferably made from a material identified as HSIIRTV manufactured by Dow Corning. Nare seal 14 has a top surface 56 which is preferably sloped for engaging the lower portion of a patient's nose including the nostrils. Nare seal 14 also includes a rearward side surface 58 which is generally perpendicular with top surface 56 for engaging the portion of a patient between the patient's mouth and nose which will be hereinafter referenced as the "upper lip". Nare seal 14 also includes left nasal seal side 60, right nasal seal side 62 and nasal seal bottom 64 which in combination with top surface 56 and rearward side surface 58 define nasal seal interior 66.

As shown in Figures 4, 5A, 6 and 7, central support 17 defines central orifice 68 which communicates with hollow bore 70. Bias ports 72 and 73 are defined within the interior wall of bore 70 on opposing sides. Nasal seal bottom 64 defines air opening 74. Nare seal 14 is mounted onto nare seal support 15 such that air opening 74 encircles central orifice 68. Bore 70 communicates with conduit receptor 19 to create a gas passageway enabling gas from positive pressure device A to enter into nare seal interior and ultimately breathed by a patient. Gas deflector 76 is positioned within the interior of bore 70 for deflecting gas received by conduit connector into nare seal interior. Gas deflector 76 includes stem 78 having opposing flanges 80, 82, 84 which is received by bore interior 70 and laterally opposing deflecting wings 86 and 88 which extend into nare seal interior. Air deflector deflects the gas from the positive pressure source into nare seal interior so that the gas encircles the patient's nares to provide a comfortable breathing environment.

Top surface 56 and rearward side surface 58 define orifice 90 which encircles the nares of the patient when gas is supplied under positive pressure. Orifice 90 is preferably diamond shaped and centrally located on top surface 56 and rearward side surface 58 such that a front portion 92 of top surface 56 may engage the bottom tip of a patient's nose while left and right side portions 94 and 96 of top surface 56 may engage the sides of a patient's nostrils and bottom and left and right side portions 98, 100 and 102 of rearward side surface 58 may engage the upper lip of the patient for sealing nare seal 14 around the patient's nares.

As shown in Figures 5, 5A and 7, nare seal 14 has a first uninflated position illustrated by broken lines 104 when gas is not being provided to the patient. In the first uninflated position, top surface 56 rests against the bottom of the patient's nose

and rearward surface 58 rests against the upper lip of the patient. When gas is being provided, nare seal has a second inflated position illustrated by solid lines 106 wherein top surface 56 deflects upward and rearward surface 58 deflects rearwardly against the patient's upper lip to encircle the patient's nares and seal the area surrounding the patient's nares.

As further shown in Figures 3 and 4, nare seal support 15 includes support arms 16 and 18 and central support 17. Preferably, nare seal support 15 is formed from an integral unitary plastic piece wherein support arms 16 and 18 extend outward from central support 17 for engaging the face of the patient preferably at the cheek bones and ultimately for connecting with headgear assembly C. Support arms 16 and 18 are configured for transferring the force required to maintain nare seal 14 in a sealed orientation with the patient's nares to the cheekbones of the patient. Support arms 16 and 18 are mirror images of one another. Support arm 16 includes a first portion 108 which extends rearwardly from central support 17 a general distance and deflects at an obtuse angle at deflection point 110. Second portion 112 of support arm 16 continues rearwardly from deflection point 110 and terminates at distal end 114. Second portion 112 has a curved interior surface for matingly contouring with a patient's face. A respective of contact connector 48 is carried by the exterior of distal end 114. Distal end 114 includes an interior surface which is convex for positioning contact connector 48 generally perpendicular to contact connector located at first depending arm 30. A first facial pad 116 is carried by the interior of support arm 16 for contact with a patient's face. Support arm 18 being a mirror image of support arm 16 has similar components such as first portion 118, deflection point 120, second portion 122, distal end 124 and contact connector 46.

Thus, it can be seen that an advantageous construction of a nasal mask and headgear assembly may be had according to the invention. The small profile of the nare seal provides sufficient sealing for maintaining positive pressure within the airway of the patient while minimizing intrusion onto the face of the patient providing for a comfortable sleeping environment. The headgear assembly in combination with the contact connectors enables the nare seal to be quickly and easily attached and disattached should the patient need to remove the mask upon waking during the sleep period and reattached for subsequent sleeping. The lateral arms of the mask support removes any

supporting force from the patient's nose and positions the force onto a bone structure which is more suitable for supporting the nare seal.

While a preferred embodiment of the invention has been described using specific terms, such description is for illustrative purposes only, and once the innovative features of the invention are known, it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims:

What is claimed is:

1. A nasal mask assembly for providing gas from a gas source to a patient, said mask assembly comprising:

a nare seal having a top surface for engaging a lower portion of a patient's nose including the nostrils,

an orifice disposed within said upper surface for encircling the nares of a patient; and

said nare seal being adapted to interconnect with a gas source.

2. The nasal mask assembly of claim 1 wherein said nare seal includes a lower surface, said upper and lower surfaces defining a nare seal interior, said lower surface defining a gas opening for communicating gas to said nare seal interior.

3. The nasal mask assembly of claim 2 wherein said interior includes a plurality of spatial regions and wherein said nasal mask assembly further includes a gas distribution assembly interposed between a gas source and said interior, wherein said gas distribution assembly comprises a plurality of channels, each of said plurality of channels being adapted to distribute gas from the gas source to one of said plurality of spatial regions.

4. The nasal mask assembly of claim 3 wherein said gas distribution assembly includes one or more flanges for channeling the gas into said plurality of spatial regions.

5. The nasal mask assembly of claim 1 wherein said nare seal further includes a rearward surface generally perpendicular to said top surface, said top surface and said rearward surface configured to engage a patient's nostril and upper lip for enclosing and sealing the nares of a patient.

6. The nasal mask assembly of claim 5 wherein said top surface and said rearward surface of said nare seal define an orifice which encircles the nares of the patient when gas is supplied to said nare seal.

7. The mask assembly of claim 1 wherein said nare seal includes a flexible membrane.

8. The mask assembly of claim 1 wherein said nare seal top surface is moveable from a first uninflated position wherein said top surface does not seal the area around the nares of the user and a second inflated position for pressing against the area around the nares of the patient when gas is supplied to said nare seal.

9. A nasal mask assembly for providing gas from a gas source to a patient comprising:

- a nare seal having a surface for encircling the nares of a patient, said nare seal defining a gas opening permitting gas from a gas source to enter into the nares of a patient; and

- a nare seal support carrying said nare seal.

10. The nasal mask assembly of claim 9 wherein said nare seal support includes a first and second lateral arm for spanning the face of a patient.

11. The nasal mask assembly of claim 10 wherein said lateral arms extend outward from a central support and deflect at an obtuse angle for engaging the face of a patient.

12. A nasal mask assembly of claim 11 further including a head gear assembly which comprises:

- a first depending arm carrying a first connector; and

- a second depending arm carrying a second connector;

- said first lateral arm including a lateral arm connector for releasably attaching to said first connector of said first depending arm;

- said second lateral arm including a second lateral arm connector for releasably attaching to said second connector of said second depending arm and head gear assembly.

13. A nasal mask assembly of claim 12 wherein said first connector and said second connector enables said nare support to be positioned at varying angles enabling said nare seal to be positioned at various positions for encircling the nares of a patient.

14. A headgear assembly for supporting a mask comprising:

- a first support member having a first forward lateral arm, a first rearward lateral arm interconnected with and extending rearwardly from said first forward lateral arm, and a first depending arm extending downward;

- a second support member having a second forward lateral arm, a second rearward lateral arm interconnected with and extending rearwardly from said second forward lateral arm, and a second depending arm extending downward;

- said first and second forward lateral arms being matingly adapted for interconnection with one another;

said first and second rearward lateral arms being matingly adapted for interconnection with one another;

said first depending arm carrying a connector for carrying a first side of a mask; and

said second depending arm carrying a connector for carrying a second side of a mask.

15. The headgear of claim 14 wherein said first and second support members are semi-rigid for maintaining a circular shape when interconnected.

16. A respiratory mask assembly for providing gas from a gas source to a patient, said respiratory mask assembly comprising:

a headgear assembly having a pair of downwardly extending members;

a pair of lateral members carried by said pair of downwardly extending members, said pair of lateral members being connected to said pair of downwardly extending members at a point below the patient's ears, wherein said pair of lateral members extend horizontally from said pair of downwardly extending members toward the front of the patient's face; and

a respiratory mask connected to said lateral members.

17. The respiratory mask assembly of claim 16 wherein said lateral arms abut a face of a patient.

18. The respiratory mask assembly of claim 16 wherein said respiratory mask includes a nare seal having a surface for encircling the nares of a patient, said nare seal defining a gas opening permitting gas from a gas source to enter into the nares of a patient.

19. A respiratory mask for providing gas from a gas source to a patient, said respiratory mask comprising:

a mask body defining a mask body interior, said interior having a plurality of spatial regions; and

a gas distribution assembly interposed between a gas source and said mask body interior, wherein said gas distribution assembly comprises a plurality of channels, each of said plurality of channels being adapted to distribute gas from the gas source to one of said plurality of spatial regions.

20. The respiratory mask of claim 19 wherein said gas distribution assembly includes one or more flanges for channeling the gas into said plurality of spatial regions.

21. The respiratory mask of claim 19 wherein said gas distribution assembly includes at least one bias port in one of said plurality of channels and at least one bias port in another one of said plurality of channels.

22. A respiratory mask for providing gas from a gas source to a patient, said respiratory mask comprising:

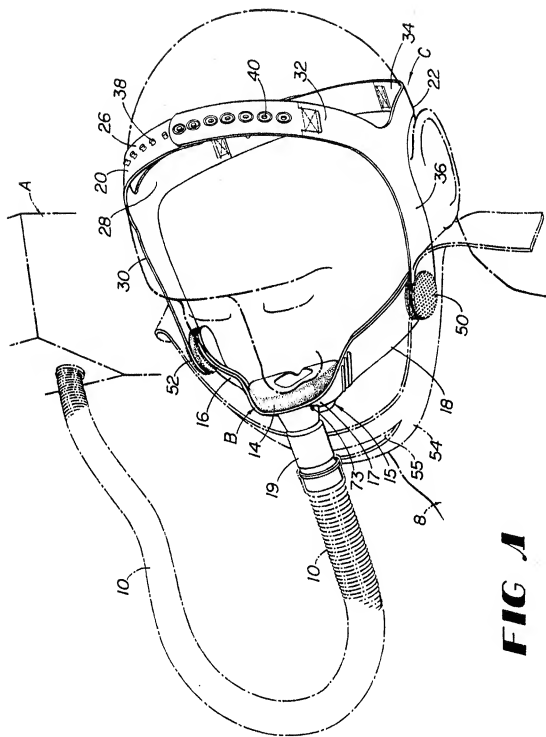
- a mask body defining a mask body interior, said interior having a plurality of spatial regions;

- a gas distribution assembly interposed between a gas source and said mask body interior, wherein said gas distribution assembly comprises a plurality of channels, each of said plurality of channels being adapted to distribute gas from the gas source to one of said plurality of spatial regions;

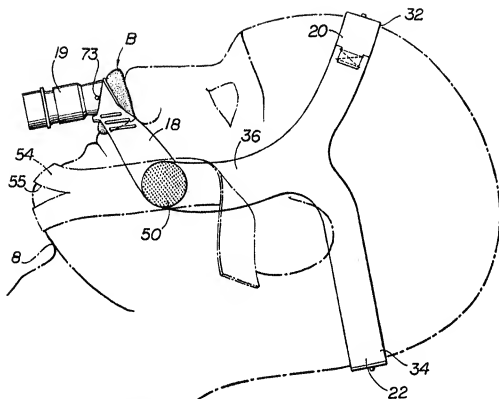
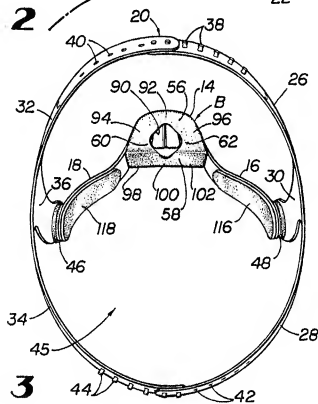
- said mask body including a nare seal having a top surface for engaging a lower portion of a patient's nose including the nostrils; and

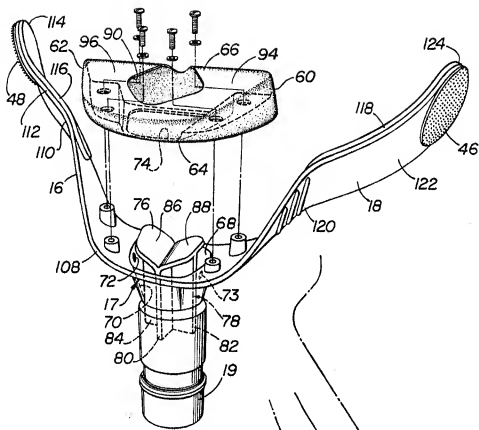
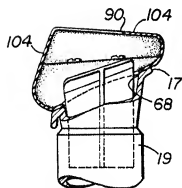
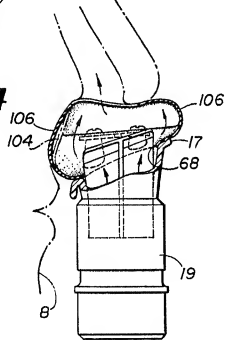
- an orifice disposed within said upper surface for encircling the nares of a patient.

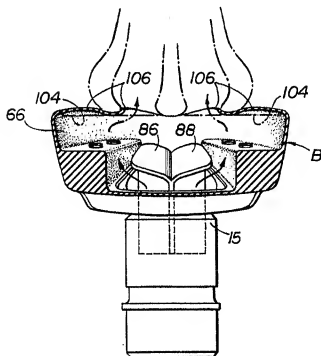
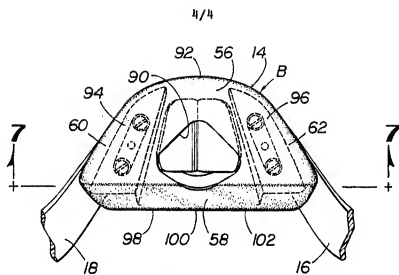
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**FIG. 1**

2/4

**FIG 2****FIG 3**

**FIG 4****FIG 5****FIG 5A**



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/15588

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 16/00; A62B 7/00, 18/02; F16K 31/02

US CL : 128/204.23, 207.13

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.23, 206.18, 207.13, 206.26, 207.18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P ----- Y,P	US 5724965 A (HANDKE et al) 10 March 1998, entire document.	1-13, 19, 20, 22 ----- 21

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*G* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

23 OCTOBER 1998

Date of mailing of the international search report

09 NOV 1998

Name and mailing address of the ISA/US
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Facsimile No. (703) 305-3230

Authorized officer
Kimberly Asher
KIMBERLY ASHER

Telephone No. (703) 308-0332

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/15588**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-13, 19-22

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US98/15588

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-13 and 19-22, drawn to a mask assembly.

Group II, claims 14-18, drawn to head gear assembly.

Groups I and II, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same, or corresponding special technical features for the following reasons: Group I lacks the special technical features of the head gear of Group II.